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|---|---|
| RAWLINGS, STEPHEN L | |

| ART UNIT | PAPER NUMBER |
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| 1643 | |

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/049,608 | GELBER, COHAVA | |
| | Examiner | Art Unit | |
| | Stephen L. Rawlings, Ph.D. | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-36 and 38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020212;20030530*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The election with traverse filed May 4, 2006, is acknowledged and has been entered.

Applicant has elected the invention of Group V, claim 37, drawn to a method for detecting the presence and extent of ovarian cancer in a patient, said method comprising determining the level of expression of an antigen in a sample of bodily fluid.

2. Claims 1-44 are pending in the application. Claims 1-36 and 38-44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 4, 2006.

3. Claim 37 is currently under prosecution.

### *Election/Restrictions*

4. Applicant's grounds of traversal of the restriction and election requirement set forth in the Office action mailed November 4, 2005, are acknowledged. Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that it would not be a serious burden to have to search the entire application, or more particularly the subject matter encompassed by claims 37 and 38 directed to the inventions of Groups V and VI, because a search of one would involve a search of the other. In response, this application was filed under 35 U.S.C. § 371; therefore, the criteria for determining lack of unity are indicated by PCT Rules 13.1 and 13.2. The "burden of search" is not a criterion upon which the propriety of the restriction and election requirement is determined in this application; as such, Applicant's argument is moot.

Accordingly, the restriction and election requirement set forth in the Office action mailed November 4, 2005, is deemed proper and therefore made FINAL.

***Information Disclosure Statement***

5. The information disclosures filed February 12, 2002, and May 30, 2003, have been considered. An initialed copy of each is enclosed.

***Priority***

6. Applicant's claim under 35 USC § 120 for benefit of the earlier filing date of PCT Application No. PCT/US02/21574, filed August 8, 2000, is acknowledged.

However, claim 37 does not properly benefit under 35 U.S.C. § 120 by the earlier filing date of the priority document claimed, since that claim is rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under 35 USC § 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely September 16, 2002.

***Specification***

7. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark is American Type Culture Collection™, which appears, e.g., at page 5, line 5, of the specification.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite for the following reason: Claim 37 is directed to a method for detecting the presence and extent of ovarian cancer in a patient. Although the claim recites the active step of correlating the quantity of the antigen in a sample of bodily fluid from the patient, the claim does not clearly and particularly indicate how performing the process steps necessarily achieves the objective or purpose of the invention. How does the quantity of the antigen in a sample of bodily fluid from the patient correlate with the presence and extent of ovarian cancer in the patient? What quantity of the antigen in a sample of bodily fluid from the patient indicates the presence and extent of ovarian cancer in the patient? The language of claim 37 does not provide a certain, unambiguous answer to these questions. Absent the requisite clarity and particularity necessary to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, the metes and bounds of the subject matter that Applicant regards as the invention cannot be ascertained so as to permit the skilled artisan to know or determine infringing subject matter.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not

> permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

*Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention*.

In this instance, claim 37 is directed to a method for detecting the presence and extent of ovarian cancer in a patient comprising determining the level of the antigen of claim 16 in a sample of bodily fluid from the patient, and correlating the quantity of said antigen with the presence and extent of said ovarian cancer cells in the patient.

Claim 16 is directed to a genus of isolated surface antigens of human ovarian cancer cells, which are further characterized in that (a) they are single polypeptides with a molecular weight of about 76 kDa to about 213 kDa, as determined by SDS PAGE under reducing conditions; (b) they are not expressed by, or absent from human peripheral blood mononuclear cells, human B cells, and human B cell myelogenic leukemia cells; and (c) they are glycosylated.

The genus of isolated surface antigens of human ovarian cancer cells includes but is not limited to a surface antigen that is further characterized in that it binds to a

monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450.

Accordingly, claim 37 is directed to a genus of surface antigens of human ovarian cancer cells, which may vary substantially in size, structure, and/or function.

Despite their common expression at the surface of ovarian cancer cells, and their lack of expression by human peripheral blood mononuclear cells, B cells, and B cell myelogenic leukemia cells, the skilled artisan could not immediately envision, recognize or distinguish at least a substantial number of the members of this genus of surface antigens to which the claim is directed. Although the specification describes with reasonable particularity one species of the genus of surface antigens to which the claim is directed, namely a glycoprotein that binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450, the specification fails to describe how this single species of surface antigen is regarded as representative of the genus, as a whole. Moreover, the specification fails to describe any one particularly identifying (i.e., substantial) structural feature of the glycoprotein that binds this antibody, which is shared by other members of the genus of surface antigens, and which correlates with any one particularly identifying functional feature, which is also shared by at least most of the genus, which might permit the skilled artisan to distinguish members of the genus from other antigens.

It is understood that certain well characterized surface antigens of human ovarian cancer cells, which are described by the prior art, are not included in the genus to which claim 37 is directed. For example, it is understood that TAG-72, a glycoprotein expressed at the surface of ovarian cancer cells and shed into the serum of patients afflicted with the disease, is not included in this genus. Although TAG-72 has a molecular weight of about 72 kDa, which approximates the requisite molecular weight of about 76 kDa, the human myelogenous leukemia cell line K562, for example, expresses detectable levels of the protein; therefore, it is apparent that claim 37 is not directed to TAG-72, because the claims requires the antigen to be absent from such cells. Similarly, it is understood that CA 125 is not included in the genus of surface antigens to which the claim is directed. While CA 125 is a glycoprotein having a molecular weight

in the requisite range, which is shed into the serum of patients afflicted with ovarian cancer, high serum levels of the protein have been observed in patients afflicted with leukemia and lymphomas. Nevertheless, mere description of features that *do not* characterize the surface antigen, so as to distinguish the claimed invention from the prior art, rather than a description of those features that *do* characterize the surface antigen, fails to satisfy the written description requirement, because such a disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

The Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). As discussed in greater detail below in the rejection of claims as lacking a sufficiently enabling disclosure, there is in fact such unpredictability in the relevant art, which would preclude the skilled artisan from immediately recognizing or distinguishing the members of the genus of surface antigens to which claim 37 is directed.

"[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). In this instance, there is no language that adequately describes the genus, as a whole, of surface antigens expressed by ovarian cancer cells, which are secreted into a biological fluid of a patient afflicted with ovarian cancer, and which upon detection and quantification provide an indication of the presence and extent of the disease in the patient. A description of what a material does, or how it is to be used, rather than of what it is, does not suffice to describe the claimed invention.

Furthermore, the Federal Circuit has stated the written description requirement set forth under 35 U.S.C. § 112, first paragraph, applies to all types of inventions. "Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to the subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds

from non-infringing compounds, or infringing methods from non-infringing methods". *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1894 (CAFC 2004). The claimed method depends upon discovering and characterizing the surface antigens to which claim 37 is directed; without such surface antigens, it is impossible to practice the invention.

Although the skilled artisan could potentially identify antigens expressed at the surface of ovarian cancer cells, which could be detected and quantified in practicing the claimed invention, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Finally, Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of surface antigens of ovarian cancer cells, which vary both structurally and functionally, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings,

or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. In this instance, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; Applicant has not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Applicant has not described distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention at the time the application was filed.

12. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for using** a process for detecting the presence and extent of ovarian cancer in a patient, said process comprising determining the level of the antigen that binds specifically to the monoclonal antibody produced by the deposited hybridoma having the ATCC accession no. PTA-450[1] in a sample of bodily fluid from the patient, and correlating the quantity of said antigen with the presence and extent of said ovarian cancer cells in the patient, **does not reasonably provide enablement for using** a process for detecting the presence and extent of ovarian cancer in a patient comprising determining the level of an antigen in a sample of bodily fluid from the patient, and correlating the quantity of said antigen with the presence and extent of said ovarian cancer cells in the patient, wherein said antigen is further characterized in that (a) it is a single polypeptides with a molecular weight of about 76 kDa to about 213 kDa, as determined by SDS PAGE under reducing conditions; (b) it is absent from human peripheral blood mononuclear cells, human B cells, and human B cell myelogenic leukemia cells; and (c) it is glycosylated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

MPEP § 2164.01 states:

[1] Here, there is a presumption that Applicant has or will provide assurance that all required deposits have been made to satisfy the requirements set forth under M.P.E.P. § 608.01 (p)(c). See M.P.E.P. § 2404.03.

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

The amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

As explained in the written description rejection above, claim 37 is directed to a genus of isolated surface antigens of human ovarian cancer cells that includes but is not limited to a surface antigen that is further characterized in that it binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450.

The genus of isolated surface antigens of human ovarian cancer cells to which claim 37 is directed may vary substantially in size, structure, and/or function, provided they are further characterized in that (a) they are single polypeptides with a molecular weight of about 76 kDa to about 213 kDa, as determined by SDS PAGE under reducing conditions; (b) they are not expressed by, or absent from human peripheral blood

mononuclear cells (PBMC), B cells, and B cell myelogenic leukemia cells; and (c) they are glycosylated.

Members of the genus of surface antigens need not share any substantial structural homology with the glycoprotein that binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450. The surface antigens need not have any particular biologic function.

Although the glycoprotein that binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450 may be overexpressed in ovarian cancer, which is shed into the blood of patients afflicted by the disease, the skilled artisan cannot predict which of the many other structurally and functionally disparate glycoproteins to which the claim is directed are also useful in detecting the presence and extent of the disease according to the claim.

Even among closely related protein family members, the skilled artisan cannot predict whether a particular member of the family is associated with the etiology or pathology a specific disease, solely on the basis that another member of the family has been shown to be. De Plaen et al. (*Immunogenetics.* 1994; **40**: 360-369), for example, reviews the structure, chromosomal localization and expression of twelve genes encoding members of the MAGE family of proteins; see entire document (e.g., the abstract). De Plaen et al. teaches six of the members of the gene family were found to be expressed at a high level in a number of tumors of various histological types; while five were very weakly expressed in all samples tested, and one, namely MAGE 7, was not transcribed at all in the ninety-five tumor samples tested (page 367, column 1). Just as not all members of the MAGE family of proteins are associated with cancer, particularly, since is it not obvious what, if any, association the weakly expressed MAGE proteins have, it is apparent that the skilled artisan cannot predict, based upon the information disclosed in the specification, whether variants of the glycoprotein that binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450, as members of a presumed family of structurally related proteins, are associated with the etiology or pathology of ovarian cancer (e.g., whether

the genes encoding such variants are differentially expressed in ovarian cancer, or whether they are shed into the bodily fluids of patients afflicted with the disease).

Furthermore, Skolnick et al. (*Trends in Biotechnology.* 2000; **18** (1): 34-39), for example, discloses that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see, e.g., the abstract; and page 34, *Sequence-based approaches to function prediction*). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see, in particular, the abstract and Box 2).

Consequently, the claimed invention could not be practiced without undue and/or unreasonable experimentation, as it would first be necessary to identify surface antigens that are suitably used in practicing the claimed invention.

Applicant is reminded, reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

Thus, the overly broad scope of claim 37 would merely serve as an invitation to one skilled in the art to identify a surface antigen, which could be used in practicing the claimed invention; yet, defining a substance by its principal biological activity or any recognizable feature amounts to an alleged conception having no more specificity than that of a wish to know the identity of any material with that biological property or feature. See *Colbert v. Lofdahl*, 21 USPQ2d 1068, 1071 (BPAI 1991).

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/012674 A1.

WO 01/012674 A1 (Gelber) teaches a determination of the level of an antigen in a sample of bodily fluid using an antibody designated Moab 69 (or alternatively, VAC69) aids in the detection and diagnosis of ovarian cancer; see entire document (e.g., abstract; page 8, lines 8-13; page 25, line 10, through page 26, line 6; and page 28, lines 2-15). Gelber teaches the antigen has a molecular weight of about 76 kDa to about 213 kDa, as determined by SDS-PAGE under reducing conditions; see, e.g., page 3, lines 25-27. Gelber teaches the antigen is glycosylated and expressed at the surface of ovarian cancer cells; see, e.g., page 5, lines 26-28. Gelber teaches the antigen is not detected in human peripheral blood mononuclear cells, human B cells, and human chronic myelogenic leukemia cells; see, e.g., page 3, lines 27-29.

***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 37 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 11/332,849. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claim 6 of the copending application is drawn to a method for detecting the presence and extent of ovarian cancer in a patient comprising determining the level of the antigen bound to by an antibody produced by the deposited hybridoma having

ATCC accession No. PTA-450 in a sample of bodily fluid from the patient, and correlating the quantity of said antigen with the present and extent of said myeloma or ovarian cancer cells in the patient.

Claim 37 of the instant application is directed to a method for detecting the presence and extent of ovarian cancer in a patient comprising determining the level of the antigen of claim 16 in a sample of bodily fluid from the patient, and correlating the quantity of said antigen with the presence and extent of said ovarian cancer cells in the patient.

Claim 16 of the instant application is directed to an isolated surface antigen of human ovarian cancer cells, said antigen being further characterized in that (a) it is a single polypeptide with a molecular weight of about 76 kDa to about 213 kDa, as determined by SDS PAGE under reducing conditions; (b) it is absent from human peripheral blood mononuclear cells, human B cells, and human B cell myelogenic leukemia cells; and (c) it is glycosylated, and which according to claim 17 is further characterized in that it binds to a monoclonal antibody produced by the deposited hybridoma having ATCC accession No. PTA-450.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

17. No claim is allowed.

18. The art made of record and not relied upon is considered pertinent to Applicant's disclosure. Krueger et al. (*J. Immunother.* 2001 Jul-Aug; **24** (4): 334-344) teaches an antigen that is expressed by ovarian tumors; the antigen is recognized by monoclonal

antibody VAC69. Krueger et al. (Cancer Immunol. Immunother. 2003 Jun; 52 (6): 367-377) teaches antigens expressed by ovarian tumors; these antigens are recognized by monoclonal antibodies VAC37.14 or VAC51.2.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
July 5, 2006